K091963

## 510(k) SUMMARY

### Infinite Biomedical Technologies' Vigilant 2.0 Monitor

**Infinite Biomedical Technologies, LLC**
**3600 Clipper Mill Road, Suite 410**
**Baltimore, MD 21211**

Phone: (410) 889-8011
Facsimile: (410) 889-8012
Contact Person: Manan Hathi
Date Prepared: 21 January 2008

NOV - 6 2009

**Name of Device and Name/Address of Sponsor**

Vigilant 2.0 EEG Monitor

Infinite Biomedical Technologies, LLC
3600 Clipper Mill Road, Suite 410
Baltimore, MD 21211

**Common or Usual Name**

Electroencephalograph

**Classification Name**

Electroencephalograph (CFR 882.1400, Class II)

**Predicate Devices**

EXCEL TECH. LTD.'s Xltek EP-16 headbox (K992313) (Electroencephalograph, CFR 882.1400, GWQ)

EXCEL TECH. LTD.'s NeuroWorks EEG (K980214) (Electroencephalograph, CFR 882.1400, GWQ)

**Intended Use / Indications for Use**

The Vigilant EEG Monitor (Vigilant 2.0) is an electroencephalograph that works in conjunction with Vigilant bedside monitoring and remote review software. It is intended for measuring and recording the electrical activity of a patient's brain by applying 8 electrodes on the head.

The Vigilant EEG Monitor (Vigilant 2.0) requires competent user input, and its output must be reviewed and interpreted by trained medical professionals who will exercise professional judgment in using this information.

**Technological Characteristics**

The Vigilant EEG Monitor (Model Vigilant 2.0) is a multi-channel EEG monitor. It is intended for monitoring the state of the brain by applying electrodes to a patient's head. It also includes software to enable remote monitoring by a neurologist or other trained personnel. Both acquisition and review of patient data can be performed at the bedside.

The Vigilant EEG Monitor does not include a computer monitor or video camera, but these are required for system use.

The Vigilant EEG Monitor consists of an EEG acquisition console with junction box and a software CD (bedside EEG monitoring software, server software for remote telecommunications and software for remote monitoring of EEG data). The principal component of the Vigilant EEG monitor is a Porti amplifier and power supply provided by TMS International (Oldenzaal, The Netherlands). The software is designed to be loaded onto an off the shelf computer monitor that may be supplied by the user. It is also designed to interface with a video camera for real-time video monitoring concurrently with EEG monitoring. Neither the computer nor the camera is considered part of the medical device.

The EEG signal display can be configured in a reduced mode (up to 4 EEG channels plus quantitative EEG metrics for each channel) or a full mode (up to 8 EEG channels). The display modes and channel display are configurable by the user.

In the reduced mode display, the user may select to display either the spectral edge frequency (SEF 95) as a line graph, or the power spectrum (POWER) displayed as four colored line graphs, each representing the standard EEG frequency bands (delta: 0-4Hz, RED; theta: 4-8Hz, YELLOW; alpha: 8-13Hz, GREEN; beta: 13-30Hz, BLUE).

Real-time video of the patient from the system camera is displayed in a separate window from the EEG signals. This window may be hidden or resized by the user. The video is recorded in synchronization with the EEG even when it is not displayed and may be replayed during review mode.

**Performance Data**

Laboratory testing demonstrated that the Vigilant EEG Monitor meets its design and functional requirements. Actual device functions and features were evaluated against the device specifications and in all instances the Vigilant Monitor performed as expected and no unexpected behavior was observed. The device meets the requirements for safety of medical electrical equipment, electromagnetic compatibility, and the particular standard for electroencephalographs.

**Substantial Equivalence**

The Vigilant Monitor is as safe and effective as the Xltek EP-16 headbox and the Natus/Xltek NeuroWorks software. The Vigilant EEG Monitor has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Vigilant EEG Monitor and its predicate devices raise no new issues of safety or effectiveness. Thus, the Vigilant 2.0 Monitor is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Infinite Biomedical Technologies, LLC
c/o Mr. Manan Hathi
3600 Clipper Mill Road, Suite 410
Baltimore, Maryland 21211

NOV - 6 2009

Re: K091963
Trade/Device Name: Vigilant EEG Monitor, Vigilant 2.0
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OMC
Dated: October 23, 2009
Received: October 26, 2009

Dear Mr. Hathi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K091963

Device Name: Vigilant 2.0 EEG Monitoring System

Indications for Use:

The Vigilant EEG Monitor (Vigilant 2.0) is an electroencephalograph that works in conjunction with Vigilant bedside monitoring and remote review software. It is intended for measuring and recording the electrical activity of a patient's brain by applying 8 electrodes on the head.

The Vigilant EEG Monitor (Vigilant 2.0) requires competent user input, and its output must be reviewed and interpreted by trained medical professionals who will exercise professional judgment in using this information.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices



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